K092476



## 5. 510(K) SUMMARY

[As Required by 21 CFR 807.92]
Summary of Safety and Effectiveness

| | | |
|---|---|---|
| 1 | Submitter | SPORT-ELEC S.A.<br>Route de Rouen BP 35<br>27520 Bourgtheroulde<br>France<br>MAY - 7 2010 |
| | Contact Person | Karine Coral / Sylviane Lardeur<br>Phone number : (+33) 2 32 96 50 50<br>Fax number : (+33) 2 32 96 50 59 |
| | Preparation date | Jan 20th 2009 |
| 2 | Device name | Body Control System "4M" |
| | Trade Name | SPORT-ELEC® |
| | Common Name | Muscle stimulator |
| | Code product and classification name | Stimulator, muscle, powered for muscle conditioning (NGX)<br>21 CFR Section 890.5850<br>Powered Muscle Stimulator |
| 3 | Predicate devices | SPORT-ELEC Body Control System, manufactured by<br>Sport-Elec REF BCS K 081026 Cleared Nov 5th 2008<br>Sport-Elec REF BCS AT K 091865 Cleared Nov 13th 2009<br>Sport-Elec REF BCS BS K 092142 Cleared Feb 5th 2010 |
| 4 | Description | Body Control System "4M" is a 2 channel battery operated muscle stimulation system specifically designed to exercise the muscles, It comprises namely an electronic stimulator module which generates the required stimulation signals.<br>Body Control System "4M" comprises 4 electrodes, which connects the signals from the stimulator to the skin. (EXHIBIT C)<br>The product is supplied with a User's Guide and a carry case. |
| | Explanation of how the device operates | Power is supplied from 3 batteries located in a compartment protected by a removable battery cover. The user cannot access the wiring or connectors . |
| | Intended use | The Body Control "4M" is intended for use by healthy persons to apply trans-coetaneous electrical muscle stimulation (EMS) through skin contact electrodes for the following purposes<br>-improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas |

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| 5 | Performance data | Testing was carried out to assure compliance with recognized electrical safety standards:<br>IEC 60601-1 and -2-10 standards for electrical safety<br>IEC 60601-1-2 standard for electromagnetic compatibility<br>IEC 60601-1-4 standard for the software (ISO 14971).<br>Performance data were also verified versus the requirements of the FDA Guidance for Pre Market Submissions and for Software contained in Medical Devices. |
| 6 | Substantial equivalence summary | The technological characteristics, features, specifications, materials, mode of operation, and intended use of the Body Control System "4M" device are substantially equivalent to the predicate devices quoted above.<br>The differences that exist between the devices do not raise new issues of safety or effectiveness regarding the Body Control System Device.<br>The Body Control System "4M" use the same as the BCS system in its delivery of the stimulation signal and has similar parameter setting. There are similar restrictions between the two devices in that electrode positioning is governed by the user manual. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sport-Elec S.A.
% Ms. Camille D. Thornton, M.S.
Regulatory Specialist
144 Research Drive
Hampton, Virginia 23666

MAY - 7 2010

Re: K092476
Trade/Device Name: Body Control System "4M"
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: NGX
Dated: April 27, 2010
Received: April 28, 2010

Dear Ms. Thornton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

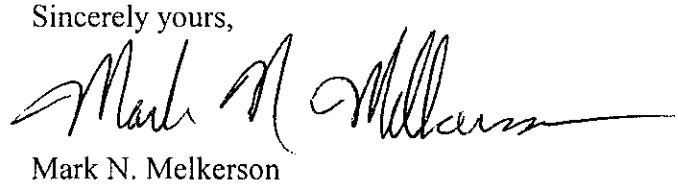
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 4. INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Body Control System "4M"

Indications for Use: Body Control System 4M is indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas.

Contraindicated use on injured or otherwise impaired muscles

Not intended for use in any therapy or for the treatment of any medical conditions or diseases

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K092476